

### Remarks

Claims 1 to 66 were pending. By this Amendment, claims 2, 6, 11 to 14, 24, 40 to 58, 61, and 62 were cancelled and claims 1, 3 to 5, 7 to 10, 15 to 23, 25 to 39, 59, 60, and 63 to 66 were amended. Claims 1, 3 to 5, 7 to 10, 15 to 23, 25 to 39, 59, 60, and 63 to 66, as amended, are now pending and before the Examiner.

The Examiner rejected claims 5 to 7, 10, 32, 43, 45, and 47 under 35 U.S.C. § 112, second paragraph as allegedly indefinite.

In response, applicants have amended claim 10 and traverse the rejection as to the other claims. The compound codes recited in the claims that cited by the Examiner are not trademarks or tradenames but compound designations that are commonly known to those of skill in the art as such and are therefore not indefinite. Applicants therefore respectfully request that the Examiner reconsider and withdraw the rejection. *etc*

The Examiner rejected claims 1 to 12, 23 to 32, 39, 40, and 63 to 66 under 35 U.S.C. § 103(a) as allegedly unpatentable over Nishimura *et al.* (Allergology Int'l, 3/1999) in view of Banholzer *et al.* (U.S. Patent No. 5,610,163). The Examiner also rejected claims 13 to 22, 33 to 38, 41 to 58, 61, and 62 under 35 U.S.C. § 103(a) as allegedly unpatentable over Nishimura *et al.* in view of Banholzer *et al.* and further in view of Gennaro *et al.* (*Remington Pharmaceutical Sciences*, 18<sup>th</sup> ed. 1990, pp. 1694-1699 and 1706-1707).

In response, applicants respectfully traverse the Examiner's obviousness rejection and contend that the rejection is improper as applied to the amended claims. A *prima facie* case of obviousness requires the satisfaction of three criteria: (i) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings; (ii) there must be a reasonable expectation of success; and (iii) the references when combined must teach or suggest all of the claim limitations. See M.P.E.P. § 2143.

The Examiner has not considered how the chemical and physical differences between (a) tiotropium salts and (b) ipratropium bromide and oxitropium bromide would militate against the combination proposed by the Examiner and would certainly not provide the required reasonable expectation of success. Rejecting claims solely by finding prior art corollaries for *how would they?*

the claimed elements would permit an Examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention, which is an illogical and inappropriate process by which to determine patentability. *Sensonics, Inc. v. Aerosonic Corp.*, 38 U.S.P.Q.2d 1551, 1554 (Fed. Cir. 1996); *In re Rouffet*, 47 U.S.P.Q.2d 1453 (Fed. Cir. 1998). Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion or incentive to do so. *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). Virtually all inventions are combinations of old elements. *Environmental Designs, Ltd. v. Union Oil Co.*, 218 U.S.P.Q. 865, 870 (Fed. Cir. 1983); *Richdel, Inc. v. Sunspool Corp.*, 219 U.S.P.Q. 8, 12 (Fed. Cir. 1983). Applicants therefore respectfully request that the Examiner reconsider and withdraw these rejections.

Applicants submit that all the pending claims are allowable and respectfully solicit a Notice of Allowance for all of the pending claims. If the Examiner feels that a telephone interview would be helpful in advancing prosecution of this application, the Examiner is invited to contact the attorney below.



**Version of the Claims with Markings to Show Changes Made by this Amendment**

In accordance with 37 C.F.R. § 1.121(c)(1)(ii), the following marked up version of the claims amended herein is provided to show all of the changes relative to the previous version of the claims before the amendments herein.

--1. (Amended) An inhalable powder pharmaceutical composition comprising:

- (a) ~~an anticholinergic~~ tiotropium salt; ~~and~~
- (b) a steroid; ~~and~~
- (c)

~~optionally together with a pharmaceutically acceptable excipient selected from glucose, arabinose, lactose, saccharose, and maltose;~~

~~the anticholinergic and the steroid optionally in the form of their enantiomers, mixtures of their enantiomers, their racemates, their solvates, or their hydrates.--~~

--3. (Amended) The inhalable powder pharmaceutical composition according to claim 2, wherein the ~~anticholinergic is a~~ tiotropium salt ~~is with a counter ion selected from~~ tiotropium chloride, tiotropium bromide, tiotropium iodide, tiotropium p-toluene sulfonate, or tiotropium methylsulfate.--

--4. (Amended) The inhalable powder pharmaceutical composition of claim 3, wherein the tiotropium salt ~~counter ion~~ is tiotropium bromide.--

--5. (Amended) The inhalable powder pharmaceutical composition according to claim 1, wherein the steroid is selected from the group consisting of: flunisolide, beclomethasone, triamcinolone, budesonide, fluticasone, mometasone, ciclesonide, rofleponide, GW 215864, KSR 592, ST-126, and dexamethasone.--

--7. (Amended) The inhalable powder pharmaceutical composition according to claim 3, wherein the steroid is selected from the group consisting of: flunisolide, beclomethasone, triamcinolone, budesonide, fluticasone, mometasone, ciclesonide, rofleponide, GW 215864, KSR 592, ST-126, and dexamethasone.--

- 8. (Amended) The inhalable powder pharmaceutical composition according to claim 3, wherein the steroid is selected from the group consisting of: flunisolide, beclomethasone, triamcinolone, budesonide, fluticasone, mometasone, ciclesonide, and dexamethasone.--
- 9. (Amended) The inhalable powder pharmaceutical composition according to claim 1, wherein the weight ratios of the anticholinergic to the steroid are in the range of from 1:300 to 50:1.--
- 10. (Amended) The inhalable powder pharmaceutical composition according to claim 7, wherein the weight ratios of the tiotropium salt to the ~~antihistamine~~steroid are in the range of from 1:250 to 40:1.--
- 15. (Amended) The inhalable powder pharmaceutical composition of claim 1, wherein the excipient has a maximum average particle size of up to 250  $\mu\text{m}$ .--
- 16. (Amended) The inhalable powder pharmaceutical composition of claim 13, wherein the excipient has a maximum average particle size of up to 250  $\mu\text{m}$ .--
- 17. (Amended) The inhalable powder pharmaceutical composition of claim 13, wherein the excipient has a maximum average particle size of up to 250  $\mu\text{m}$ .--
- 18. (Amended) The inhalable powder pharmaceutical composition of claim 15, wherein the excipient has a maximum average particle size of up to 250  $\mu\text{m}$ .--
- 19. (Amended) The inhalable powder pharmaceutical composition of claim 15, wherein the excipient has a maximum average particle size of between 10  $\mu\text{m}$  and 150  $\mu\text{m}$ .--
- 20. (Amended) The inhalable powder pharmaceutical composition of claim 16, wherein the excipient has a maximum average particle size of between 10  $\mu\text{m}$  and 150  $\mu\text{m}$ .--
- 21. (Amended) The inhalable powder pharmaceutical composition of claim 17, wherein the excipient has a maximum average particle size of between 10  $\mu\text{m}$  and 150  $\mu\text{m}$ .--

--22. (Amended) The inhalable powder pharmaceutical composition of claim 18, wherein the excipient has a maximum average particle size of between 10  $\mu\text{m}$  and 150  $\mu\text{m}$ .--

--23. (Amended) A capsule containing ~~at~~the inhalable powder pharmaceutical composition according to claim 1 ~~in the form of an inhalable powder~~.--

--25. (Amended) A capsule containing ~~at~~the inhalable powder pharmaceutical composition according to claim 3 ~~in the form of an inhalable powder~~.--

--26. (Amended) A capsule containing ~~at~~the inhalable powder pharmaceutical composition according to claim 4 ~~in the form of an inhalable powder~~.--

--27. (Amended) A capsule containing ~~at~~the inhalable powder pharmaceutical composition according to claim 5 ~~in the form of an inhalable powder~~.--

--28. (Amended) A capsule containing ~~at~~the inhalable powder pharmaceutical composition according to claim 6 ~~in the form of an inhalable powder~~.--

--29. (Amended) A capsule containing ~~at~~the inhalable powder pharmaceutical composition according to claim 7 ~~in the form of an inhalable powder~~.--

--30. (Amended) A capsule containing ~~at~~the inhalable powder pharmaceutical composition according to claim 8 ~~in the form of an inhalable powder~~.--

--31. (Amended) A capsule containing ~~at~~the inhalable powder pharmaceutical composition according to claim 9 ~~in the form of an inhalable powder~~.--

--32. (Amended) A capsule containing ~~at~~the inhalable powder pharmaceutical composition according to claim 10 ~~in the form of an inhalable powder~~.--

--33. (Amended) A capsule containing ~~at~~the inhalable powder pharmaceutical composition according to claim 13 ~~in the form of an inhalable powder~~.--

--34. (Amended) A capsule containing a~~the~~ inhalable powder pharmaceutical composition according to claim ~~14~~20 ~~in the form of an inhalable powder.~~--

--35. (Amended) A capsule containing a~~the~~ inhalable powder pharmaceutical composition according to claim 15 ~~in the form of an inhalable powder.~~--

--36. (Amended) A capsule containing a~~the~~ inhalable powder pharmaceutical composition according to claim 16 ~~in the form of an inhalable powder.~~--

--37. (Amended) A capsule containing a~~the~~ inhalable powder pharmaceutical composition according to claim 17 ~~in the form of an inhalable powder.~~--

--38. (Amended) A capsule containing a~~the~~ inhalable powder pharmaceutical composition according to claim 18 ~~in the form of an inhalable powder.~~--

--39. (Amended) A pharmaceutical composition consisting essentially of:

- (a) ~~an anticholinergic~~ tiotropium salt; and
- (b) a steroid,

wherein the pharmaceutical composition is in the form of an inhalable powder.--

--59. (Amended) A method of treating inflammatory or obstructive diseases of the respiratory tract in a patient in need of such treatment; the method comprising administering to the patient a therapeutically effective amount of the pharmaceutical composition according to one of claims 1 to 12.--

--60. (Amended) The method according to claim 59, wherein the disease is chronic obstructive pulmonary disease (COPD) or asthma ~~pharmaceutical composition is administered to the patient by inhalation after nebulizing the pharmaceutical composition into an inhalable aerosol using an energy operated free standing or portable nebulizer that produces inhalable aerosols by means of ultrasound or compressed air.~~--

--63. (Amended) A kit comprising one or more unit dosage containers containing a pharmaceutical composition, each unit dosage container containing a pharmaceutical composition comprising:

- (a) ~~an anticholinergenic~~ tiotropium salt; and
- (b) a steroid,

each optionally together with a pharmaceutically acceptable excipient;

~~the anticholinergic and the steroid optionally in the form of their enantiomers, mixtures of their enantiomers, their racemates, their solvates, or their hydrates.--~~

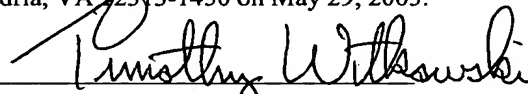
--65. (Amended) A kit comprising:

- (a) a first container containing a first pharmaceutical formulation comprising an anticholinergic tiotropium salt; and
- (b) a second container containing a second pharmaceutical formulation comprising a ~~comprising a~~ steroid,

each container each optionally further containing a pharmaceutically acceptable excipient, ~~the anticholinergic and the steroid optionally in the form of their enantiomers, mixtures of their enantiomers, their racemates, their solvates, or their hydrates.--~~

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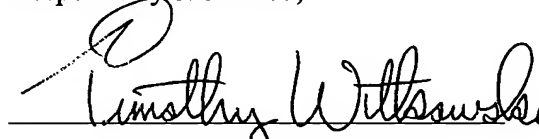


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